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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,870	08/06/2001	Bernhard Palsson	PALSSN.002C1	1729
<div>41552 7590 09/11/2007 MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122</div>				
			EXAMINER ZEMAN, MARY K	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 09/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/923,870	Applicant(s) PALSSON, BERNHARD	
	Examiner Mary K. Zeman	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-54, 56-62 and 64-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-54 56-62 64-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1631, Examiner Mary Zeman.

Applicant's arguments filed 6/14/07 have been fully considered but they are not persuasive. Rejections not repeated below have been withdrawn.

The declaration of Dr. J. Edwards under 37 CFR 1.132 filed 6/14/07 is insufficient to overcome the rejection of the claims based upon 35 USC 112, first paragraph as set forth in the last Office action and will be addressed below.

Claim Rejections - 35 USC § 101

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 49, 51-54, 56, 57, 59-62 and 64-65 remain rejected and new claims 66 and 67 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The examiner has carefully considered the rejection of record and Applicant's arguments and amendments.

With regard to claim 49: the claim has been amended to recite "providing an output to a user of a genome specific stoichiometric matrix..." The inclusion of an output step alone does not render the claimed method statutory. The result which is output must meet the standard of being concrete, tangible and useful. The "matrix" is a list of numbers, and names which requires further interpretation to be useful. In and of itself the "matrix" is merely a dimensionless pile of data. Further, it is not clear that one obtains a matrix each time the method is run for **any** microbe, therefore the result is unpredictable or not concrete.

With regard to claim 53, there is not transformation of matter, and there is no output of a concrete, tangible and useful result. The "in silico representation" does not meet the standard of concrete, tangible and useful. It is not tangible as it remains in the computer. It is not concrete as it is unpredictable for the scope of the claim.

With regard to claim 54, it is unclear at what point the limitations are added- before or after the newly added output step. If the final step of the method of claim 54 is the "flux balance

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been developed for the required systems analysis of metabolism.... The complete sequencing of a bacterial genome and ORF assignment provides the information needed to determine the relevant metabolic reactions that constitute metabolism in a particular organism. Thus a flux-balance model can be formulated and several metabolic analyses can be performed to extract metabolic characteristics for a particular organism. The flux balance approach can be easily applied to systematically simulate the effect of single, as well as multiple, gene deletions. This analysis will provide a list of sensitive enzymes that could be potential antimicrobial targets.” To achieve a realistic, accurate model, the highest amount of detailed information is required. One of skill in the art at the time the invention was made would have assumed that all metabolic genes are required for simulation, as the effect of having fewer than all reactions accounted for was not known. Pramanik et al. described a stoichiometric model of E. coli metabolism using flux-balance modeling techniques (Stoichiometric Model of Escherichia coli Metabolism: Incorporation of Growth-Rate Dependent Biomass Composition and Mechanistic Energy Requirements, Biotechnology and Bioengineering, Vol. 56, No. 4, November 20, 1997). However, the analytical methods described by Pramanik, et al. can only be used for situations in which biochemical knowledge exists for the reactions occurring within an organism. It was not known at the time which reactions created a “minimal set” sufficient for accurately modeling the metabolic behavior of E. coli or any other microbe. Therefore, at the time the invention was made one of skill in the art of molecular modeling would have attempted to use “most” or “all” of the DNA sequences and metabolic reactions of a microbial genome to carry out the methods of the claims. Using fewer than all would have required undue experimentation to determine what is and is not necessary for life, or its accurate simulation.

f) The skill of those in the art of molecular biology is high.

g) The prior art predicts that using less than all the known reactions for a given organism would result in a faulty and inaccurate in silico model and matrix for that organism. .

h) The claims are broad because they are drawn to methods some unidentified and unspecified subset of molecular reactions for simulation and matrix generation..

The skilled practitioner would first turn to the instant specification for guidance to identify what number and kind of DNA sequences from a microbial genome constitute an amount “sufficient to produce an in silico representation of a microbe”. However, the instant

specification does not provide specific guidance to practice these embodiments. As such, the skilled practitioner would turn to the prior art for such guidance, however, the prior art shows that the results of deleting metabolic reactions or genes from a molecular simulation were unpredictable. Finally, said practitioner would turn to trial and error experimentation to determine what genes and reactions constitute a minimal set sufficient to produce an in silico representation of each and every organism desired. Such represents undue experimentation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272 0720. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

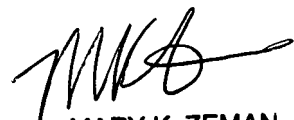
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of

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the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


MARY K. ZEMAN
PRIMARY EXAMINER
